ENVIRONMENTAL LAW & POLICY CENTER
Protecting the Midwest's Environment and Natural Heritage

September 25, 2009

Dr. Thomas Armitage
Designated Federal Officer
EPA Scientific Advisory Board (1400F)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington D.C., 20460

Re: Empirical Approaches for Nutrient Criteria Derivation Draft Guidance Document

Dear Dr. Armitage:

The Mississippi River Collaborative (the "Collaborative") is pleased to present to the Science Advisory Board these comments which consist principally of the attached "Comments on U.S. EPA's draft document, 'Empirical Approaches for Nutrient Criteria Derivation' by U.S. EPA" by Dr. JoAnn Burkholder. The Collaborative is a group of organizations working together to improve water quality in the Mississippi River, its tributaries and the Gulf of Mexico. On July 30, 2008, the Collaborative filed its Petition for Rulemaking under the Clean Water Act: Numeric Water Quality Standards for Nitrogen and Phosphorus and TMDLs for the Mississippi River and the Gulf of Mexico (the "Petition") to U.S. EPA.

In addition to presenting the comments of Dr. Burkholder, the Collaborative wishes to mention five points. These points, while obvious to most people familiar with the relevant science and regulatory principles applicable to setting water quality standards, have been ignored by many who have heretofore offered comments in this matter.

First, it is absolutely critical that numeric standards to control nitrogen and phosphorus be established as soon as possible. The ongoing serious effect of nitrogen and phosphorus on the nation's rivers, lakes and estuaries was documented in the Petition and in many U.S. EPA findings. It was further underscored by the recent serious outbreaks of cyanobacteria affecting drinking water in Iowa and other states. Further, as recognized by the August 26, 2009 Inspector General's Report, "while setting standards does not improve water quality, it generally marks the beginning of serious efforts to identify impaired waters and make improvements where needed."

Second, as discussed by Dr. Burkholder, the draft document under review discusses only one of the ways by which numeric nutrient criteria may be derived. Generally, most water quality criteria, of course, are developed through laboratory studies. The available laboratory studies indicate that noxious algal blooms may develop at nutrient levels only slightly higher than those present in waters unimpacted by anthropogenic sources of nutrients. Accordingly, criteria at

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least as strong as the reference water-based criteria developed by U.S. EPA in 2001 are suitable and should be used if the stressor-response based analysis is rejected for a given parameter, state or type of water body.

Third, while there must be a "sound scientific rational" for water quality standards (40 CFR § 131.11), standards for pollutants have been and must be set even when a simple and direct relationship between pollutant concentrations and biological endpoints cannot be set forth with mathematical certainty. Most of our water quality standards are set by killing organisms in a laboratory, or by feeding nutrients to algae in a flask, although no one claims that there is a simple relationship between any given pollutant concentration level that will kill test organisms or stimulate algal blooms and the concentration of the pollutant that will impair water bodies. Outside the laboratory, there are always complicating factors that prevent a simple stressor-response relationship. To protect the biological integrity of the nation's waters, using reasonable estimates combined with various safety factors is unavoidable.

In fact, drawing reasonable lines based on past practice and experience is both proper and a very common regulatory function. Administrative agency regulatory numerical standards are lawfully established if they are "within a zone of reasonableness." *Hercules Inc. v. EPA*, 598 F.2d 91, 107-08 (D.C. Cir. 1978). *See also*, *Reynolds Metal Co. v. United States EPA*, 760 F.2d 549, 558 (4th Cir. 1985) (upholding EPA numerical standard).

Fourth, the problem of drawing relationships between nitrogen and phosphorus levels and water body health must be considered in light of the fact that many of our nation's waters now have levels of nitrogen and phosphorus that, based upon available evidence from sediment cores, are far in excess of natural levels, and few or no proper reference waters remain. It is hardly surprising that it is difficult to find tight relationships between phosphorus levels and stream ecological health in states where most or all of the streams available to study now have extremely high amounts of nitrogen and phosphorus. If one compared the health of gunshot victims who had been shot 20 times with those shot 30 times, it is unlikely that statistically significant differences could be found.

The fact that all or almost all of the water bodies in a state have far too much phosphorus and nitrogen does not mean that that state should not have numeric nitrogen and phosphorus standards. However, the standards set for such states (e.g. Illinois, Indiana, Iowa) may have to be set using relationships developed from studying waters in states that are less nutrient over-enriched (e.g. Montana and Wisconsin).

More generally, for the states lacking the necessary data or expertise to apply the stressor – response approach, the state (or EPA) should use a different approach to setting criteria or adopt criteria developed by states with the necessary data or expertise.

Finally, the clear intent of some who have submitted comments to explicitly or implicitly inject economic considerations into the criteria setting process must be rejected. The only way in which the applicable federal regulations allow consideration of economic factors in setting water quality standards relates to designation of uses for particular water bodies for which it is sought to rebut the presumption that all water bodies are to be fishable and swimmable. Under 40 C.F.R.

131.10 (g)(6), a state may remove a designated use (that is not an existing use) if it is shown that pollution controls needed to protect that use would "result in substantial and widespread economic and social impact." Economic factors may *not* be taken into account in setting the numeric standards that are protective of uses. Water quality criteria must protect the "most sensitive use." 40 C.F.R. 131.11(a); see also. Mississippi Commission on Natural Resources v. Costle, 625 F.2d 1269, 1277 (5th Cir. 1980).

In short, to protect the nation's waters from nitrogen and phosphorus pollution, EPA must do the best it can to make reasonable estimates based on available data and may not design criteria to attain a result that is economically palatable. Timing and implementation of the criteria can involve policy choices, but those are to be made *after* protective criteria are developed.

Sincerely,

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Comments on U.S. EPA's draft document, "*Empirical Approaches for Nutrient Criteria Derivation*"
(2009 draft for Science Advisory Board review)

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This draft document written by the U.S. Environmental Protection Agency (EPA) first briefly describes three approaches that can be used to set numeric nutrient criteria: (1) reference condition, (2) stressor-response analysis, and (3) mechanistic modeling. It explains that the focus of this writing is to provide more details about how to use approach (2), stressor-response analysis, following a five-step process, with considerable flexibility built into each step. The intent of the document is to assist States, Territories, and authorized Tribes that choose to include stressor-response relationships as a basis for their nutrient criteria development programs.

The data evaluation and analytical tools presented for each of the five steps are sound. Once some additional information is included, this guidance will be very helpful in using stressor-response analysis to develop nutrient criteria. The following comments are offered in the spirit of strengthening this document for its intended use.

EPA stated (p.3) that "The purpose of this empirical approaches guidance document is to provide information on the scientific foundation for using empirical approaches to describe stressor-response relationships for deriving nutrient criteria". It would help for EPA to state its purpose even a bit more clearly: this is an explanatory document only, written for statisticians and modelers who are assisting state agencies and other entities as mentioned above.

EPA also should explain that the focus here is on ambient nutrient concentrations, rather than nutrient loadings, because nutrient concentrations are key variables supporting algal assemblage shifts, excessive algal production, and associated adverse effects of nutrient over-enrichment (Hecky and Kilham 1988). In addition, stressor-response approaches should be better defined. As Tetra Tech (2008) wrote, "Stressor-response approaches refer to a suite of analytical techniques that derive candidate endpoints by exploring and identifying thresholds in the relationships between response variables and nutrient concentrations".

As part of the description of the five-step process to use stressor-response analysis, the EPA draft document discusses data requirements for each statistical tool described (pp.20-40), and how to evaluate and account for uncertainties in the statistical model selected (pp.43-52). Some good examples are included about appropriate choice and application of various statistical tools. Use of supporting references would strengthen the writing in some places. For example, in Step 1, the conditional probability approach enables identification of risks of impact associated with given nutrient concentrations, so it is well suited for use in identifying nutrient thresholds that protect aquatic life (Paul and McDonald 2005, Tetra Tech 2008). This explanation with supporting references should be added.

The reason why EPA wrote this document seems very clear: The concept of a reference condition is scientifically well-founded (e.g. Stoddard et al. 2006), and use of a reference condition (where such conditions still exist) as a basis for developing numeric nutrient criteria is fairly straightforward (see discussion in Tetra Tech 2008). In contrast, stressor-response analysis can involve an array of various data evaluation and statistical tools. Hence, this guidance from EPA was contributed to help states (etc.) understand how this approach can be undertaken. The document does *not* stress that one of the three approaches is better or worse than another; in fact, the document repeatedly indicates that the choice largely depends upon the water body and the data available. It also does *not* state that EPA is going to require states to use the stressor-response analysis approach. A difficulty with use of the stressor-response approach is that the EPA guidance depends, and must depend, upon the states (etc.) having the necessary expertise to evaluate their data appropriately and apply the most applicable statistical tools for analysis and interpretation. The document as it stands simply offers guidance in data evaluation and analysis in applying one of three approaches to develop nutrient criteria.

Although EPA's nutrient criteria guidance (p.1) recommends that criteria be derived for total nitrogen (TN) and total phosphorus (TP) as causal variables, EPA states that this recommendation or guidance "does not

preclude the use of alternative causal or response variables". I strongly recommend that development of nutrient criteria consider inorganic N (nitrate and ammonia). EPA also recommends that criteria should be derived for "primary" response variables chlorophyll *a* (indicator of algal biomass) and water clarity. EPA suggests, as well (p.1), inclusion of several additional variables such as dissolved oxygen, trophic state indices, and biocriteria (e.g. macroinvertebrate communities).

This document would be strengthened by the addition of an introductory section that explains the extremely strong scientific basis underlying the need for nutrient criteria. The document cannot "stand alone" without it. In this added section, first, the point should be made that it is past time to develop nutrient criteria, considering that the National Research Council has reported that the majority of our nation's waters are degraded from nutrient pollution. Information such as nutrient concentrations that are clearly, significantly (based upon standard statistical analyses) in excess of reference stream conditions (= excessive) is a justifiable approach. However, reference streams are hard to come by in most regions of our country because nutrient pollution is chronic and pervasive (e.g. National Research Council 2000). Second, the added introductory section should include mention of the many scientific publications that have established nutrient over-enrichment as a major source of water quality degradation in the nation and the world (e.g. Schindler 1977, Caraco 1993, Vitousek et al. 1997, Smil 2001). Third, the section should present an extended summary of the wealth of peer-reviewed, published, correlative field data, backed by controlled experiments, that have related nutrient over-enrichment to water quality degradation. This explanation should include some of the many classic examples in the published literature of how correlative relationships between nutrients and various response variables from field data, backed by supporting bioassays and other experimental information, have repeatedly demonstrated causality between stressor-response relationships such as increased nutrients vs. increased algal biomass in surface waters across the nation. This introductory information is needed because it is the foundation for EPA's guidance here and in various other publications referenced (e.g. US EPA 2000a,b).

In the "Step 2" section, EPA should provide clearer guidance on what it will consider sufficient information to support development of numeric criteria. The draft writing describes that most stressor-response analyses of nutrients and response variables are based upon empirical field data; relationships estimated from such observational data can be confounded by other co-varying factors; and laboratory studies can provide stronger supporting evidence to support cause and effect. EPA then discusses various approaches for assessing the strength of the cause-effect relationship. However, the document also should clarify the data that States, Territories and authorized Tribes will need to have in hand for use in developing numeric nutrient criteria. Such information has been provided to states, after all, in developing other numeric nutrient criteria, and in developing total maximum daily loads for various pollutants. This information will help guide States, Territories and authorized Tribes regarding the status of their data so that they can select the most appropriate statistical tools to use (e.g. to help interpret Table 1, p.44 of this document which mentions data requirements as "moderate" or "high" without providing guidance on what that means). As part of this explanation, such terms as "moderate" and "high" amounts of data should be defined more clearly.

Some critics of this document assert that the draft guidance oversimplifies the many factors by which nutrients cause increased algal growth, oxygen levels and other ecological problems. On the contrary, EPA acknowledges throughout the document that the relationship between nutrients and response variables such as algal blooms can be complex, and that the effects can be direct or indirect. EPA also specifically mentions an array of potential response variables such as chlorophyll *a* (algal biomass), oxygen levels, macroinvertebrate community changes etc. For example, EPA (p.5) states that "a response variable that is causally related to nutrients but whose effect may be obscured by other factors may require a model with multiple explanatory variables to accurately estimate the effects of nutrients". Much of the remainder of the document provides guidance on how to handle such complexities with statistical tools and models. Light, hydrology (flow and water residence time), grazer abundance, etc. sometimes must be considered in such models, depending upon the system. Far from ignoring such factors, this draft guidance is designed to help states (etc.) *consider* them when data evaluation indicates that such consideration is necessary.

Critics also assert that site-specific data must be in hand, including strong correlative field data and supporting experimental data, before numeric nutrient criteria can be established and applied. This stance,

however, overlooks the fact that numeric standards for other factors, such as dissolved oxygen or enterococci densities, are applied to the waters across a designated general area based upon (i) correlative field data for only some of those waters, and (ii) from a much smaller set of representative locations, supporting peer-reviewed, published literature demonstrating cause and effect in appropriately designed laboratory experiments. The numeric standards for other parameters are applied across the waterways *without* requiring the same exhaustive field and experimental work to be completed for every specific location. It stands to reason, for example, that low dissolved oxygen stresses the health of aquatic life and can cause fish disease and death.

It would be illogical to require that the cause-effect relationship should have to be re-demonstrated in every site of every waterway to which the dissolved oxygen standard is applied, complete with intensive data collection at every site. Logically, enterococci densities that have been linked to human illness in one system, supported by appropriate laboratory experiments, very likely cause human health problems in similar systems as characterized by available field data. Therefore, resource managers err on the side of caution to proactively protect human health in setting conservative (that is, low) numeric criteria for enterococci densities based upon field data for the waters, supported by published information – collected previously, and usually in other aquatic systems – about cause-effect.

Moreover, proof of a cause-and-effect relationship at each site logically implies that one must wait until a water body has been harmed to even assign a standard. This certainly is not consistent with the purpose of protecting water bodies from harm.

Knowledge about excessive nutrient concentrations that have been linked to algal blooms, organic enrichment and decomposition, low dissolved oxygen, the loss of sensitive species, or other response variables in freshwaters of a given area, is commonly applied to other freshwaters of the area. Depending upon the type of waters being considered, the area grouped is a geographic region (for example, the lakes of a state, or more broadly, shallow north temperate lakes), or the rivers of a watershed (NC DENR 1997). Numeric nutrient criteria should be developed to ensure that the most sensitive waters – usually the most poorly flushed waters (Wetzel 2001) – within the area being considered are protected.

The draft document tacitly considers the points contained in the above three paragraphs, but EPA should more explicitly state them, perhaps at the end of the added introductory section as the overarching rationale for the guidance. Overall, inclusion of the information recommended in these comments will make this helpful guidance document even stronger in meeting EPA's goal of providing assistance to states (etc.) in using stressor-response analysis to develop numeric nutrient criteria.

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